

UNITED STATES DISTRICT COURT JUDGE SCHOFIELD
SOUTHERN DISTRICT OF NEW YORK

MARVIN A. EATON, Individually and on
Behalf of All Others Similarly Situated,

Plaintiff(s),

v.

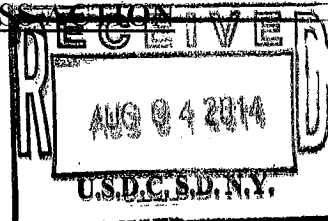
EDAP TMS S.A., MARC
OCZACHOWSKI, and ERIC SOYER,

Defendants.

Case No.

14 CV 6069

CLASSIFICATION



DEMAND FOR JURY TRIAL

COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

Plaintiff Marvin A. Eaton ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding EDAP TMS S.A., ("EDAP" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of a class consisting of all persons and entities, other than Defendants (defined below) and their affiliates, who purchased American Depositary Receipts (“ADR”) of EDAP on the NASDAQ Exchange (“NASDAQ”) from February 1, 2013 to July 30, 2014, inclusive (the “Class Period”). Plaintiff seeks to pursue remedies against EDAP and certain of its officers and directors for violations of the federal securities laws under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Defendant EDAP TMS S.A., through its subsidiaries, designs and manufactures medical equipment. The Company develops minimally invasive therapeutic ultrasound solutions for urology, tumor removal, localized prostate cancer, and related infectious diseases. EDAP purports to serve patients and medical professionals worldwide. EDAP is incorporated and headquartered in France and its ADR’s trade on the NASDAQ under the ticker symbol “EDAP.”

3. One of the most important therapeutic solutions in the Company’s pipeline is Ablatherm, a HIFU-based device for the treatment of organ-confined prostate cancer, referred to as T1-T2 stage. The Ablatherm system is intended to treat prostate cancer by ablating the entire prostate gland via high intensity focused ultrasound (“HIFU”), which generates heat of around 200 degrees Fahrenheit. There are no other HIFU devices on the market. Most men with the condition are treated with radical prostatectomy surgery, radiation or regular monitoring with delayed surgery if needed, according to the FDA.

4. Throughout the Class Period, Defendants made false and/or misleading statements, and failed to disclose material adverse facts about the Company’s business, operations, prospects and performance. Specifically, during the Class Period, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company was

overstating the efficacy and safety of its Ablatherm trials by using faulty statistical methods and presenting misleading data; (ii) the Company was understating the frequency of adverse events in its trials for Ablatherm including erectile dysfunction, urinary incontinence, and urethral and bowel injury; and (iii) as a result of the above, the Company's financial statements were materially false and misleading at all relevant times.

5. On July 28, 2014, a U.S. Food and Drug Administration ("FDA") staff report was released in anticipation of a July 30, 2014 meeting of the Gastroenterology and Urology Devices Panel Advisory Committee meeting (the "FDA Staff Report"). In the FDA Staff Report, the FDA questioned whether EDAP's methods for testing the device were adequate. Specifically, FDA staff questioned EDAP's safety and effectiveness data because the Company compared patients in two different studies to gather evidence, rather than a head-to-head trial. EDAP relied on a registry of patients in Europe who have used Ablatherm, and compared their data to a subgroup of patients in a U.S. Department of Veterans Affairs trial who underwent surgery called radical prostatectomy. Patients who used Ablatherm had a 1.1 percent risk of their cancer spreading after eight years, compared to a 1.4 percent risk for men who underwent surgery.

6. According to an article published by Bloomberg News on July 28, 2014:

[The] FDA staff report raises concerns about "clinical meaningfulness" of EDAP's data and safety of its Ablatherm Integrated Imaging device to treat low-risk, localized prostate cancer.

☐ FDA cites concerns about how efficacy data were interpreted in application, limitations in cross-study comparisons, safety profile and comparisons of the non-surgical device.

☐ FDA advisory panel will meet July 30 to review findings and make recommendations.

7. The FDA Staff Report also noted high rates of adverse events associated with Ablatherm, including erectile dysfunction and urinary incontinence, clinically significant rates of

stricture, urethral injury and bowel injury, which the Company had not properly presented in a clinically meaningful way. Specifically, the FDA Staff Report notes:

FDA Comment: Several of the separately-reported adverse event categories are related, and may be more clinically meaningful for interpretation when combined, as follows: “voiding symptoms” (e.g., bladder/urinary urgency, urinary frequency, hesitancy, incomplete bladder emptying, irritative symptoms, nocturia, lower urinary tract symptoms, etc.), “urinary retention” (e.g., urinary restriction, retention, obstruction, etc.), “stricture” (e.g., urinary stricture, urethral stenosis, bladder neck contracture, etc.), “bowel dysfunction” (e.g., constipation, diarrhea, hemorrhoidal pain, nausea, vomiting, ischemic bowel, rectal bleeding, etc.), and “urethral injury” (e.g., urethral perforation, sloughing, submucosal hematoma, etc.).

8. Also, on July 28, 2014, as a result of the FDA Staff Report, EDAP was downgraded to “Market Perform” from “Outperform” at Northland Securities by equity analyst Suraj Kalia.

9. On the news, EDAP stock fell \$1.23 in unusually heavy volume, or over 25%, to close at \$3.65 on July 28, 2014.

10. On July 30, 2014, after the close of trading, the Company issued a press release and filed a Form 6-K with the SEC, providing an update on the FDA Advisory Committee Meeting on Ablatherm. In the press release, the Company stated, in part:

EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, today announced that the U.S. Food and Drug Administration’s (FDA) Gastroenterology and Urology Devices Panel (GUDP) voted 3 yes, 5 no with 1 abstention on the question of safety, 9 no on the question of efficacy, and 8 no with 1 abstention for the risk/benefit ratio for the use of its Ablatherm-HIFU device for the treatment of low-risk, localized prostate cancer.

Marc Oczachowski, EDAP’s Chief Executive Officer, commented, “We are disappointed by the Committee’s recommendation regarding Ablatherm-HIFU for the treatment of low-risk, localized prostate cancer and we appreciate the dialogue during today’s meeting. We look forward to subsequent discussion with the FDA. We will continue to work diligently with the FDA as it carefully completes its final review for Ablatherm-HIFU’s PMA.”

11. On the news, EDAP stock fell \$1.50 on unusually heavy volume, or almost 44%, to close at \$1.92 on July 31, 2014.

JURISDICTION AND VENUE

12. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

13. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

14. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

15. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

16. Plaintiff, as set forth in the accompanying Certification, which is incorporated by reference herein, purchased the common stock of EDAP at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

17. Defendant EDAP is a French corporation with its principal executive offices located at 4 Rue du Dauphine Parc d'Activites la Poudrette Vaulx-en-Velin, 69120. ADR's of EDAP trade on the NASDAQ under the ticker symbol "EDAP."

18. Defendant Marc Oczachowski ("Oczachowski") has served at all relevant times as the Company's Chief Executive Officer ("CEO").

19. Defendant Eric Soyer (“Soyer”) has served at all relevant times as the Company’s Chief Financial Officer (“CFO”).

20. The Defendants referenced above in ¶¶ 18 and 19 are sometimes referred to herein, collectively, as the “Individual Defendants.”

21. Defendant EDAP and the Individual Defendants are referred to herein, collectively, as the “Defendants.”

SUBSTANTIVE ALLEGATIONS

Background

22. EDAP TMS S.A., through its subsidiaries, develops, produces, and markets minimally invasive medical devices for the treatment of urological diseases. The Company operates in two divisions: High Intensity Focused Ultrasound (HIFU), and Urology Devices and Services. The High Intensity Focused Ultrasound division develops, manufactures, and markets devices for the minimally invasive destruction of various types of localized tumors using HIFU technology. The Urology Devices and Service division develops, markets, manufactures, and services medical devices for the minimally invasive diagnosis or treatment of urological disorders, primarily urinary stones and other clinical indications.

23. The Company markets and sells its products through its direct marketing and sales organization, as well as through third-party distributors and agents. Its customers include public and private hospitals, urology clinics, and research institutions worldwide. The Company was founded in 1979 and is based in Vaulx-en-Velin, France.

24. One of the most important therapeutic solutions in the Company’s pipeline is Ablatherm, a HIFU-based device for the treatment of organ-confined prostate cancer, referred to as T1-T2 stage. The Ablatherm system is intended to treat prostate cancer by ablating the entire prostate gland via high intensity focused ultrasound (HIFU), which generates heat of around 200

degrees Fahrenheit. There are no other HIFU devices on the market. Most men with the condition are treated with radical prostatectomy surgery, radiation or regular monitoring with delayed surgery if needed, according to the FDA.

**Materially False and Misleading
Statements Issued During the Period**

25. On February 1, 2013, the Company issued a press release and filed a Form 6-K, announcing that it submission to the FDA of a Pre-Market Approval Application for Ablatherm. In the press release, the Company stated, in part:

EDAP TMS SA (Nasdaq: EDAP), the global leader in therapeutic ultrasound, announced today the submission of its Pre-Market Approval (PMA) application to the U.S. Food and Drug Administration (FDA) on January 31, 2013 for the Company's Ablatherm-HIFU (High Intensity Focused Ultrasound) for treatment of low risk, localized prostate cancer. EDAP's PMA submission includes data from the ENLIGHT study, a multi-center U.S. Phase II/III clinical trial that completed the two year follow-up needed to evaluate its primary endpoint in August 2012, as well as data from the Company's extensive worldwide database of treatment information and follow-up data from patients who have undergone HIFU therapy for prostate cancer.

* * *

Marc Oczachowski, Chief Executive Officer of EDAP TMS, remarked, "We have clearly seen a paradigm shift in prostate cancer, as patients are diagnosed earlier than ever before. Low risk patients need a middle ground between radical treatment, which is often overly-aggressive, and the anxiety of 'watchful waiting.' Ablatherm-HIFU is well-positioned to address this unmet medical need by providing a unique non-invasive and fully robotic treatment option."

Marc Oczachowski concluded, "The PMA submission to the FDA represents a significant milestone in the U.S. regulatory process for Ablatherm-HIFU. The EDAP team, together with its clinical, regulatory and legal advisors, has devoted six years to conducting the U.S. clinical trial that studied Ablatherm-HIFU as a treatment for localized prostate cancer. I am very proud of the team, and we will continue to work closely with the agency during the final stages of the process."

26. On February 8, 2013, the Company issued a press release and filed a Form 6-K announcing data demonstrating the safety and long-term efficacy of Ablatherm-HIFU, entitled “EDAP’s Ablatherm-HIFU Demonstrates Long-Term Efficacy and Safety Over Fourteen-Year Period.” The press release stated, in part:

Longest Retrospective Study of HIFU Patients to Date Published Confirms Benefits of Treatment

EDAP TMS SA, the global leader in therapeutic ultrasound, announced today new data demonstrating the safety and long-term efficacy of Ablatherm-HIFU, an ultrasound guided HIFU device for the treatment of localized prostate cancer. The data was electronically published in January 2013 by the British Journal of Urology, International.

Roman Ganzer, M.D., Primary Investigator and Associate Professor of Urology at the University of Regensburg in Germany, summarized, “We studied a large consecutive patient series that underwent primary HIFU for localized prostate cancer, gathering data over the longest follow-up period in current literature, with data extending out to 14 years. Our results improve the understanding of the long term cancer control of HIFU as a primary therapy for prostate cancer as well as the morbidity associated with the procedure. *The study solidifies the fact that HIFU is a safe and effective therapeutic option for patients with localized prostate cancer of low and intermediate risk profile. The morbidity experienced by patients was reasonable and, specifically, the rate of serious side effects such as recto-urethral fistulae is very low.*”

The study, titled “Fourteen-year oncological and functional outcomes of high-intensity focused ultrasound in localized prostate cancer,” was a fourteen year retrospective single-center study of 538 patients with localized prostate cancer who underwent primary Ablatherm-HIFU for clinically localized prostate cancer between November 1997 and September 2009 at the University Hospital of Regensburg (Germany). The study had a mean follow-up of 8.1 years and a range of up to 14 years. The findings included favorable oncological outcomes with biochemical disease-free survival rates at five and 10 years of 88% and 71% for low risk patients and 83% and 63% for intermediate risk patients, respectively.

John Rewcastle, Ph.D., Medical Director of EDAP TMS, remarked, “This is a landmark publication as it contains a report of 10 year biochemical outcomes with follow-up extending to 14 years. The biochemical disease free survival rates are comparable with those reported following other prostate cancer treatments and this is balanced with an attractive morbidity profile. This represents the longest follow-up of any series to date, and validates the outcomes of Ablatherm-HIFU as first line, whole gland treatment for prostate cancer.”

27. On March 28, 2013 the Company issued a press release and filed a Form 6-K, announcing that it received FDA filing acceptance of its pre-market approval application for Ablatherm. In the press release, the Company stated, in part:

EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, announced today that the U.S. Food and Drug Administration has provided a positive Filing Review Notification on the Company's Pre-Market Approval (PMA) application for its Ablatherm Integrated Imaging HIFU (High Intensity Focused Ultrasound) device for the treatment of low-risk, localized prostate cancer. The FDA conducted a filing review of EDAP's PMA, and found it to contain all of the information needed to proceed with the substantive review, in which the FDA will evaluate the safety and effectiveness of Ablatherm Integrated Imaging HIFU device, as well as EDAP's engineering, manufacturing and quality systems.

Marc Oczachowski, Chief Executive Officer of EDAP TMS, commented, "Receiving FDA filing acceptance for our PMA in less than two months is both very timely and a major milestone. We are moving forward in the PMA Review Process as the agency commences its substantive review. We will continue to work closely with the FDA review team."

28. On April 2, 2013, the Company issued a press release and filed a Form 6-K, announcing its financial and operating results for the fourth quarter and full year ended December 31, 2012. For the fourth quarter, the Company announced a net loss of \$1.43 million, or \$0.08 per diluted share on revenue of \$12.23 million, compared to a net loss of \$0.78 million or \$0.05 per diluted share on revenue of \$10.14 million for the same period in the prior year. For the year, net loss was \$9.61 million or \$0.55 per diluted share, on revenue of \$33.52 million compared to a net loss of \$1.31 million, or \$0.10 per diluted share on revenue of \$31.04 million, for the prior year.

29. In the press release, the Company stated, in part:

Mr. Oczachowski continued, "Our PMA application for Ablatherm-HIFU is steadily moving forward through the U.S. FDA review process. Last week we received notification that our PMA had been accepted for Filing Review, less than two months after we submitted the complete application to the FDA. With this significant milestone completed, we have now

entered the substantive review phase, and we are looking forward to a continuing dialog with the agency as the review process advances.”

30. On April 2, 2013, the Company filed an annual report on Form 20-F with the SEC, which was signed by defendants Oczachowski and Soyer, and reiterated the Company’s previously announced quarterly and year-end financial results and financial position. In addition, the Form 20-F contained signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) by defendants Oczachowski and Soyer, stating that the financial information contained in the Form 20-F was accurate and disclosed any material changes to the Company’s internal control over financial reporting.

31. In the Form 20-F, the Company stated, in part:

On August 17, 2012, we announced the completion of the two-year follow-up phase of all patients included in our ENLIGHT Ablatherm-HIFU multi-center U.S. Phase II/III clinical trial conducted under an Investigational Device Exemption (IDE) granted by the FDA, and started to compile the comprehensive Premarket Approval (PMA) file in view of FDA submission.

On January 31, 2013, we submitted our PMA application to the FDA for our Ablatherm-HIFU for treatment of low risk, localized prostate cancer. Our submission included data from the ENLIGHT U.S. Phase II/III clinical trial, as well as data from our extensive worldwide database of treatment information and follow-up data from patients who have undergone HIFU therapy for prostate cancer. On March 4, 2013, we received a positive administrative acceptance review notification from the FDA for our PMA application and on March 26, 2013 we received confirmation from the FDA that our PMA submission contained all of the information needed to proceed with the substantive review.

32. On May 16, 2013, the Company issued a press release and filed a Form 6-K with the SEC, announcing its financial and operating results for the first quarter ended March 31, 2013. The Company announced a net loss of \$5.13 million, or \$0.28 per diluted share, on revenue of \$7.83 million, compared to a net loss of \$4.06 million or \$0.22 per diluted share on revenue of \$6.77 million for the same period in the prior year.

33. In the press release the Company stated:

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "With total revenues up 23% year-over-year, we are continuing to see strong demand for our innovative lithotripsy product range in key global markets. In parallel, we increased our investments in both our FDA regulatory program and our U.S. sales and marketing efforts to further penetrate the U.S. market with both our technologies, which in combination contributed to the 16.5% increase in our first quarter operating expenses. Our device backlog is comprised of ten lithotripters at the midpoint of the second quarter and our team is continuing to cultivate customer leads around the world. Leveraging our aggressive marketing strategy, we anticipate seeing continuous traction in our sales across targeted geographic markets."

"As reported, we had significant attendance at our booths and recorded strong interest in both our HIFU and ESWL technologies during the two most important urology congresses in the world, the European Annual Urology (EAU) meeting in Milan, Italy, and the American Urology Association (AUA) annual meeting in San Diego, California. We have increasing momentum on both our HIFU range of devices, fueled by the launch of our innovative Focal. One® device at the EAU, and on our lithotripsy technologies propelled by a high number of live demonstrations to physicians during the AUA."

Mr. Oczachowski continued, "The FDA process for our Ablatherm-HIFU is on track as we submitted our Pre-Market Approval (PMA) application that was reviewed and approved for filing in late March. We continue working and communicating smoothly with the agency and we have a 100-day meeting scheduled with the FDA for early June to discuss our file."

34. On May 21, 2013 the Company issued a press release and filed a Form 6-K with the SEC, announcing that it entered into definitive agreements with certain institutional investors for a registered direct placement of \$12 million of ordinary shares in the form of American Depositary Shares ("ADSs") at a price of \$4.00 per share, with warrants attached.

35. In a prospectus supplement filed on May 22, 2013, the Company stated about Ablatherm, in part:

We market the Ablatherm® for high-intensity focused ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients

with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, or for patients who failed radiotherapy treatment. Ablatherm-HIFU is approved and commercialized in Europe as a treatment for prostate cancer and is currently under regulatory review in the U.S. following submission of the Pre-Market Approval Application in January 2013 after the completion of a multi-center U.S. Phase II/III clinical trial under an Investigational Device Exemption (IDE) granted by the FDA. The Company also develops its HIFU technology for the potential treatment of certain other types of tumors. EDAP TMS SA also produces and commercializes medical equipment (the Sonolith® range) for treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL).

36. About the use of proceeds from the direct placement, the Company stated, in part:

We estimate that the net proceeds of this offering, after deducting placement agent fees and our estimated offering expenses, will be approximately \$10,800,000. We intend to use a portion of the net proceeds of this offering to reimburse our Debentures issued in the exchange offer we carried out in January 2012, either immediately or over the remaining term of the Debentures. We intend to use the balance of the net proceeds to further strengthen our financial profile as well as to accelerate our investments in preparation for our market entry in the United States with Ablatherm-HIFU. See "Use of Proceeds."

The warrants issued to the investors will allow them to purchase up to 1.5 million ordinary shares. The warrants have an exercise price of \$4.25 per share and are exercisable beginning six months from the date of their issuance for a period of five years. The offering is expected to close on or about May 24, 2013 subject to satisfaction of customary closing conditions.

37. On August 28, 2013, the Company issued a press release and filed a Form 6-K with the SEC, announcing its financial and operating results for the second quarter ended June 30, 2013. Net loss was \$0.26 million or \$0.01 per diluted share, on revenue of \$5.88 million, compared to a net loss of \$3.43 million or \$0.19 per diluted share on revenue of \$7.86 million for the same period in the prior year.

38. On November 21, 2013, the Company issued a press release and filed a Form 6-K with the SEC, announcing its financial and operating results for the third quarter ended September 30, 2013. Net loss was \$0.49 million or \$0.03 per diluted share, on revenue of \$7.37

million, compared to a net loss of \$0.62 million, or \$0.04 per diluted share on revenue of \$7.1 million for the same period in the prior year.

39. That same day, the Company issued a press release and filed a Form 6-K with the SEC, announcing that it completed its response to questions from the FDA regarding the Company's Ablatherm-HIFU Pre-Market Approval ("PMA") application, closing this step within the FDA review process. In the press release, the Company stated, in part:

Marc Oczachowski, Chief Executive Officer of EDAP TMS SA, commented, "This is another significant milestone within the FDA approval process for our Ablatherm-HIFU device. As per the standard FDA review timeframe, the next step is an advisory committee meeting that we expect to be held within the next four to six months. We do not believe there will be any further questions related to the filing or additional requests from the FDA prior to the panel meeting. With this step behind us, we are focusing our efforts to be fully prepared for the upcoming panel meeting."

40. On April 3, 2014, the Company issued a press release and filed a Form 6-K, announcing its financial and operating results for the fourth quarter and full year ended December 31, 2013. For the fourth quarter, the Company announced a net loss of \$0.78 million, or \$0.04 per diluted share on revenue of \$11.01 million, compared to a net loss of \$1.43 million or \$0.08 per diluted share on revenue of \$12.23 million for the same period in the prior year. For the year, net loss was \$1.03 million or \$0.05 per diluted share, on revenue of \$14.67 million compared to a net loss of \$9.61 million or \$0.55 per diluted share, on revenue of \$33.52 million, for the prior year.

41. In the press release, the Company stated, in part:

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We are pleased with the continued progress that our PMA submission has made over the past year. Just last month, we completed the question and answer phase with the FDA. We are now advancing towards the FDA advisory panel meeting."

Mr. Oczachowski continued, "Our 2013 topline results were in line with the prior year on a constant currency basis and the year-over-year decrease in our total GAAP revenues was primarily due to the significant exchange loss of the Euro compared to the Japanese Yen. We are pleased with the strong traction of our lithotripsy business in the U.S. with a twofold sales increase in 2013. Starting in 2014, we have a record sales backlog with over fifteen lithotripters and five HIFU devices, comprised of two Focal One and three Ablatherms."

42. On April 3, 2014, the Company filed an annual report on Form 20-F with the SEC, which was signed by defendants Oczachowski and Soyer, and reiterated the Company's previously announced quarterly and year-end financial results and financial position. In addition, the Form 20-F contained SOX certifications signed by defendants Oczachowski and Soyer, stating that the financial information contained in the Form 20-F was accurate and disclosed any material changes to the Company's internal control over financial reporting.

43. In the Form 20-F, the Company stated, in part:

On January 31, 2013, we submitted our PMA application to the FDA for our Ablatherm for treatment of low risk, localized prostate cancer. Our submission included data from the ENLIGHT U.S. Phase II/III clinical trial, as well as data from our extensive worldwide database of treatment information and follow-up data from patients who have undergone HIFU therapy for prostate cancer. On June 3, 2013 we held our 100-day meeting with the FDA to discuss our PMA file with the reviewing team. Since then we have been providing all the requested additional information on our PMA file.

44. On May 15, 2014, the Company issued a press release and filed a Form 6-K, announcing its financial and operating results for the first quarter ended March 31, 2014. The Company announced net income of \$1.15 million, or \$0.06 per diluted share on revenue of \$10.64 million, compared to a net loss of \$5.13 million or \$0.28 per diluted share on revenue of \$7.83 million for the same period in the prior year.

45. In the press release, the Company stated, in part:

Marc Oczachowski, EDAP's Chief Executive Officer, stated, "We are very enthusiastic about the Company's all time record results for the first

quarter driven by a growing demand for our HIFU devices. This reflects the strong market momentum for our new Focal One HIFU technology that was introduced in Europe last summer. It is very exciting to see the growing adoption of our products among the urology community as we now have a complete and unique HIFU offering including Focal One and Ablatherm to cover most market needs. As we advance through the second quarter, we have a strong sales backlog featuring ten lithotripters and two HIFU devices and remain focused on driving product sales.”

Mr. Oczachowski continued, “Our HIFU technology has now gained a new status among the international urology community and health authorities. Just last month, France’s Ministry of Health granted national reimbursement for prostate cancer treatment procedures using HIFU and the European Association of Urology updated its guidelines to recommend HIFU as primary and salvage prostate cancer therapy. In the US, we have now moved to the next phase with our PMA application which is panel preparation, the team is currently in the interactive review process with FDA.”

46. On May 22, 2014, the Company issued a press release and filed a Form 6-K, announcing the confirmation of an FDA Panel Meeting to review Ablatherm. In the press release, the Company stated, in part:

LYON, France, May 22, 2014 (GLOBE NEWSWIRE) -- EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that the U.S. Food and Drug Administration (FDA) Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will review the Pre-Market Approval (“PMA”) application for EDAP’s Ablatherm-HIFU device for the treatment of localized prostate cancer on July 30, 2014.

Marc Oczachowski, EDAP’s Chief Executive Officer, said, “Confirmation of this important milestone is great news for the Company and its PMA application. The FDA provided us with a worksheet that details the deadlines and documents to be prepared and sent to the panel members for review ahead of the advisory committee meeting on July 30, 2014. We are very excited to now have a much clearer path toward FDA approval and the entire team at EDAP is diligently preparing for this major event in the PMA application process.”

47. On May 28, 2014, the Company issued a press release and filed a Form 6-K, providing an outline of key events that were scheduled in the Ablatherm-HIFU PMA Process. In the press release the Company stated, in part:

In addition to the previously announced panel of experts that is scheduled to review the Ablatherm-HIFU device and provide a recommendation based on the clinical data submitted to the FDA, the Company has additional milestones to achieve as part of the PMA application process. The first relates to an engineering, manufacturing and quality assessment of EDAP's factory, which consists of a routine inspection by the FDA. This has now been confirmed and scheduled to take place June 23 to June 26, 2014. In parallel there is a clinical data validation process, which includes an FDA audit of the investigation sites. The Company has received confirmation and scheduling of the "foreign" site's audit which will be conducted in the course of July 2014.

Marc Oczachowski, EDAP's Chief Executive Officer, said, "Having dates confirmed for these additional milestones is further great news for EDAP, as it demonstrates how quickly the FDA process is moving for our Ablatherm-HIFU PMA application. We are very enthusiastic to see the progression of events since our last complete submission in March of this year and consider this to be a very exciting time in the Company's history. Our experienced team is fully committed to preparing for these upcoming events so that we can execute these optimally. EDAP has successfully met the requirements of all of our previous FDA inspections and audits and is professionally organized in compliance with major quality assurance systems."

48. On May 28, 2014, the Company issued a press release and filed a Form 6-K, announcing a Registered Direct Offering which the Company expected would raise \$9.3 million.

In the press release, the Company stated, in part:

EDAP TMS SA (Nasdaq:EDAP), a global leader in therapeutic ultrasound, announced that it has entered into definitive agreements with certain institutional investors for a registered direct placement of 3 million of ordinary shares in the form of American Depositary Shares ("ADSs") at a price of \$3.11 per share. The offering is expected to close on or about June 3, 2014 subject to satisfaction of customary closing conditions.

49. In a prospectus supplement filed on May 7, 2014, the Company stated about Ablatherm, in part:

We develop and market the Ablatherm device, an advanced choice for HIFU treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option for localized prostate cancer with a low occurrence of side effects. Ablatherm is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative

option. It is also used for patients who failed a radiotherapy treatment. In addition, we are developing HIFU technology for the treatment of certain other types of tumors. In March 2013, we introduced a new robot assisted HIFU device dedicated to the focal treatment of prostate cancer, the “Focal One”, which received CE marking in June 2013. We also produce and commercialize medical equipment for treatment of urinary tract stones using ESWL.

We recently announced that the Ablatherm-HIFU FDA Panel meeting has been confirmed for July 30, 2014, our first quarter 2014 results and the decision by France’s Ministry of Health to reimburse HIFU treatment for prostate cancer. Further information is incorporated by reference to our Form 6-K, filed with the SEC on May 28, 2014 and which is stated on its cover page to be incorporated by reference into the registration statement. See “Incorporation by Reference” in this prospectus supplement.

50. About the use of proceeds from the direct placement, the Company stated, in part:

We estimate that the net proceeds of this offering, after deducting placement agent fees and our estimated offering expenses, will be approximately \$8.4 million. We intend to use the net proceeds from the sale of the securities offered hereby for operating costs, capital expenditures and for general corporate purposes, including working capital, and more particularly, for continued product development and preparatory action in advance of the review at the end of July 2014 by the U.S. Food and Drug Administration (FDA) Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee of the Pre-Market Approval (“PMA”) application for EDAP’s Ablatherm-HIFU device, as well as for any other preparatory work in connection with the PMA process. See “Use of Proceeds.”

51. The statements referenced in ¶¶ 25–50 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts, which were known to Defendants or recklessly disregarded by them, including that: (i) the Company was overstating the efficacy and safety of its Ablatherm trials by using faulty statistical methods and presenting misleading data; (ii) the Company was understating the frequency of adverse events in its trials for Ablatherm including erectile dysfunction, urinary incontinence, and urethral and bowel injury; and (iii) as a result of the above, the Company’s financial statements were materially false and misleading at all relevant times.

The Truth Emerges

52. On July 28, 2014, the FDA staff released its report in anticipation of the July 30, 2014 meeting of the Gastroenterology and Urology Devices Panel regarding the Ablatherm NDA. In the FDA Staff Report, the FDA questioned whether EDAP's methods for testing are adequate. Specifically, FDA staff questioned EDAP's safety and effectiveness data because the company compared patients in two different studies to gather evidence, rather than a head-to-head trial. EDAP relied on a registry of patients in Europe who have used Ablatherm, and compared their data to a subgroup of patients in a U.S. Department of Veterans Affairs trial who underwent surgery called radical prostatectomy. The FDA noted that the Company's measurement of how long patients lived without their disease spreading fell short of the "gold standard" measurement of overall survival. Patients who used Ablatherm had a 1.1 percent risk of their cancer spreading after eight years, compared to a 1.4 percent risk for men who underwent surgery.

53. According to an article published by Bloomberg News on July 28, 2014:

[The] FDA staff report raises concerns about "clinical meaningfulness" of EDAP's data and safety of its Ablatherm Integrated Imaging device to treat low-risk, localized prostate cancer.

- ☐ FDA cites concerns about how efficacy data were interpreted in application, limitations in cross-study comparisons, safety profile and comparisons of the non-surgical device.
- ☐ FDA advisory panel will meet July 30 to review findings and make recommendations.

54. The FDA Staff Report also noted high rates of adverse events associated with Ablatherm, including erectile dysfunction and urinary incontinence, clinically significant rates of stricture, urethral injury and bowel injury, which the Company had not properly presented in a clinically meaningful way. Specifically, the FDA Staff Report notes:

FDA Comment: Several of the separately-reported adverse event categories are related, and may be more clinically meaningful for interpretation when combined, as follows: “voiding symptoms” (e.g., bladder/urinary urgency, urinary frequency, hesitancy, incomplete bladder emptying, irritative symptoms, nocturia, lower urinary tract symptoms, etc.), “urinary retention” (e.g., urinary restriction, retention, obstruction, etc.), “stricture” (e.g., urinary stricture, urethral stenosis, bladder neck contracture, etc.), “bowel dysfunction” (e.g., constipation, diarrhea, hemorrhoidal pain, nausea, vomiting, ischemic bowel, rectal bleeding, etc.), and “urethral injury” (e.g., urethral perforation, sloughing, submucosal hematoma, etc.).

55. Also, on July 28, 2014, as a result of the FDA Staff Report, EDAP was downgraded to “Market Perform” from “Outperform” at Northland Securities by equity analyst Suraj Kalia.

56. On the news, EDAP stock fell \$1.23 in unusually heavy volume, or over 25%, to close at \$3.65 on July 28, 2014.

57. On July 30, 2014, after the close of trading, the Company issued a press release and filed a Form 6-K with the SEC, providing an update on the FDA Advisory Committee Meeting on Ablatherm. In the press release, the Company stated, in part:

EDAP TMS SA (Nasdaq:EDAP), the global leader in therapeutic ultrasound, today announced that the U.S. Food and Drug Administration’s (FDA) Gastroenterology and Urology Devices Panel (GUDP) voted 3 yes, 5 no with 1 abstention on the question of safety, 9 no on the question of efficacy, and 8 no with 1 abstention for the risk/benefit ratio for the use of its Ablatherm-HIFU device for the treatment of low-risk, localized prostate cancer.

Marc Oczachowski, EDAP’s Chief Executive Officer, commented, “We are disappointed by the Committee’s recommendation regarding Ablatherm-HIFU for the treatment of low-risk, localized prostate cancer and we appreciate the dialogue during today’s meeting. We look forward to subsequent discussion with the FDA. We will continue to work diligently with the FDA as it carefully completes its final review for Ablatherm-HIFU’s PMA.”

58. On this news, EDAP stock fell \$1.50 in unusually heavy volume, or almost 44%, to close at \$1.92 on July 31, 2014.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

59. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired EDAP ADRs on the NASDAQ during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

60. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, EDAP securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by EDAP or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

61. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

62. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

63. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of EDAP;
- whether the Individual Defendants caused EDAP to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of EDAP securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and,
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

64. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

65. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;

- EDAP securities are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased and/or sold EDAP securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

66. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

67. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

68. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

69. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

70. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions,

practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of EDAP securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire EDAP securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

71. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for EDAP securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about EDAP's finances and business prospects.

72. By virtue of their positions at EDAP, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made,

although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

73. Defendants were personally motivated to make false statements and omit material information necessary to make the statements not misleading in order to personally benefit from the sale of EDAP securities from their personal portfolios.

74. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of EDAP, the Individual Defendants had knowledge of the details of EDAP's internal affairs.

75. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of EDAP. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to EDAP's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of EDAP securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning EDAP's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired EDAP securities at artificially inflated prices and relied upon the price of the securities,

the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

76. During the Class Period, EDAP securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of EDAP securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of EDAP securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of EDAP securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

77. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

78. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

**(Violations of Section 20(a) of the
Exchange Act Against The Individual Defendants)**

79. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

80. During the Class Period, the Individual Defendants participated in the operation and management of EDAP, and conducted and participated, directly and indirectly, in the conduct of EDAP's business affairs. Because of their senior positions, they knew the adverse non-public information about EDAP's phase III clinical trials.

81. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to EDAP's future prospects, and to correct promptly any public statements issued by EDAP which had become materially false or misleading.

82. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which EDAP disseminated in the marketplace during the Class Period concerning EDAP's the conduct and results of EDAP's Phase III clinical trials. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause EDAP to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of EDAP within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of EDAP securities.

83. Each of the Individual Defendants, therefore, acted as a controlling person of EDAP. By reason of their senior management positions and/or being directors of EDAP, each of

the Individual Defendants had the power to direct the actions of, and exercised the same to cause, EDAP to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of EDAP and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

84. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by EDAP.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- D. Awarding such other and further relief as this Court may deem just and proper.

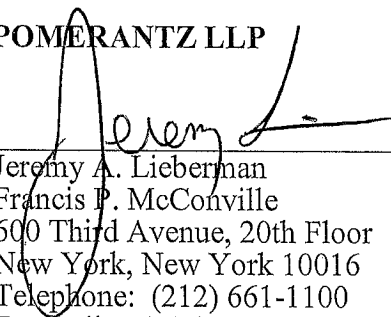
DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: August 4, 2014

Respectfully submitted,

POMERANTZ LLP



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Attorneys for Plaintiff

**CERTIFICATION PURSUANT
TO FEDERAL SECURITIES LAWS**

1. I, MARVIN A EATON, make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.
2. I have reviewed a Complaint against EDAP TMS S.A. ("EDAP" or the "Company"), and authorize the filing of a comparable complaint on my behalf.
3. I did not purchase or acquire EDAP securities at the direction of plaintiffs counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.
4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or acquired EDAP securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.
5. To the best of my current knowledge, the attached sheet lists all of my transactions in EDAP securities during the Class Period as specified in the Complaint.
6. During the three-year period preceding the date on which this Certification is signed, I have not sought to serve as a representative party on behalf of a class under the federal securities laws.
7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury that the foregoing is true and correct.

Executed 8-1-2014
(Date)

Marvin A. Eaton
(Signature)

MARVIN A. EATON
(Type or Print Name)

EDAP TMS SA (EDAP)

Eaton, Marvin IRA

LIST OF PURCHASES AND SALES

DATE	PURCHASE OR SALE	NUMBER OF SHS/UTS	PRICE PER SH/UT
07/23/2014	PUR	5,000	\$5.0700
07/23/2014	PUR	2,500	\$4.7899
07/25/2014	PUR	3,000	\$4.9001